MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McN

Individual Safety Report
3142700-X-00-01

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...roved by FDA on 11/15/93

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
01337214	19 yrs	(X) female	136 lbs
In confidence	or Date of birth: [redacted]	( ) male	or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ( ) death (mo/day/yr)
- ( ) life-threatening
- (X) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- (X) other: recovered

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
2/26/93	10/01/98

5. Describe event or problem

Notification via litigation of case summaries provided by physician/co-author of literature report (N Engl J Med 1997; 337:1112-7). Info provided based on extracted data from medical records of patients hospitalized for acetaminophen ingestion between 1/1/92 & 4/30/95. According to extracted data, pt was admitted to hospital for accidental TYLENOL overdose. Addl info rec'd 10/1/98: Med records indicate an inconsistent hx of TYLENOL use, including: 8 on Wed night, 10 Thurs, 12 Fri; approx 20 tabs in last 24 hrs; & 4-6 tabs w/ minimal relief & for approx 2 days taking approx 4 tablets 4 to 5 times per day. On presentation, pt had NAUSEA AND VOMITING & was unable to tolerate po fluids. Pt also had mild right upper quadrant pain (ABDOMINAL PAIN) & low back pain (BACK PAIN). Pt was admitted on 2/27/93 & treated with MUCOMYST®. Pt's right upper quadrant pain resolved & pt was able to tolerate po fluids & food without problems. Pt was discharged on 3/2/93. Principal discharge diagnosis listed as TYLENOL-induced hepatotoxicity (LIVER DAMAGE).

6. Relevant tests/laboratory data, including dates

2/26/93: acetaminophen level=7, Hgb=14.1, HCT=42.7, Plt=293, PT=19.1, PTT=34.3, Creat=0.9, BUN=15, AST=396, AlkP=60, GGT=28, Tbili=1.6, 2/27/93: HBsAG, a-HBC, a-HCV, a-HAVIgM (all negative), TP=7.3, Alb=3.9; (See Sect B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

no previous history of liver disease, ETOH use, or drug abuse (Sect B6 cont.) 3/2/93: PTT=32, Hgb=10.9, HCT=32.5, Plt=234, Creat=0.7, BUN=9, AST=184, ALT=641, AlkP=62, Tbili=0.9, TP=5.8, Alb=3.2, GGT=55, globulin=2.6, A/G ratio=1.2

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL® Tablets

#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 2-4g day 1, 8-10g day 2-3	#1 2/24/93-2/26/93; 3 days
#2	#2

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 left molar toothache	#1 ( ) Yes ( ) No (X) N/A
#2	#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1 Unknown	#1 Unknown	#1 ( ) Yes ( ) No (X) N/A
#2	#2	#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

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10. Concomitant medical products and therapy dates (exclude treatment of event)

ORTHO NOVUM® 7/7/7

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- ( ) literature
- ( ) consumer
- (X) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 10/01/98

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- ( ) initial (X) follow-up # 1

8. Adverse event term(s)

OVERDOSE ACCID
NAUSEA VOMIT
PAIN ABDOMINAL
PAIN BACK
LIVER DAMAGE

9. Mfr. report number: 0904077A

E. Initial reporter

1. Name, address & phone #

[redacted] Medical Ctr [redacted]

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2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA

Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.